India

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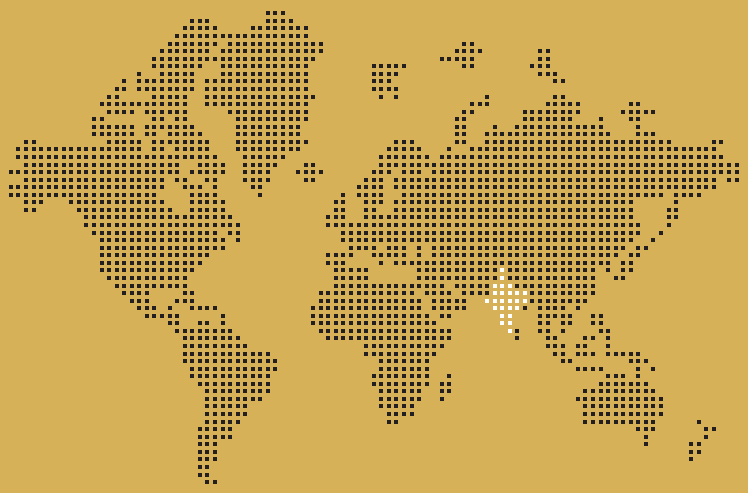

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Selection, clearance and registration

Regulatory bodies and requirements

Trademarks Registry
An applicant can apply to the registrar of trademarks to register a trademark under the provisions of the Trademarks Act 1999. The applicant must file for registration at the Trademarks Registry within whose territorial limits the applicant has its principal place of business or address for service. The registry then examines the application to evaluate its compliance with the requirements of the Trademarks Act.

A sign qualifies for registration if it is a 'trademark' as defined in the Trademarks Act. Section 9 provides that the trademark applied for can be refused registration on the grounds that it:

- is not distinctive;
- is customary in the current language or common to trade; or
- causes confusion or deception to the public.

Section 11 provides grounds for refusal of registration of a trademark where it is identical or similar to an earlier trademark and the rival goods or services are also identical or similar. Registration of a mark that is identical or similar to a well-known mark is also prohibited, no matter whether the rival goods or services are different, if the use of the subsequent mark is detrimental to the distinctiveness or reputation of the well-known mark. Further, a trademark is prohibited from registration if its use is liable to be prevented by the law of passing off or copyright.

Under Section 12, the registrar may allow registration on the grounds of honest concurrent use or under any other special circumstances.

Section 13 prohibits registration of a trademark if it is:

- the commonly used and accepted name of any single chemical element or single chemical compound in respect of a chemical substance or preparation; or
- declared by the World Health Organization and notified by the registrar as an international non-proprietary name (INN) or is deceptively similar to such name.

Intellectual Property Appellate Board
All appeals from decisions of the registrar are referred to the Intellectual Property Appellate Board (IPAB) as constituted under the Trademarks Act. Section 91 requires appellants to bring any appeal before the IPAB within three months of receipt of the disputed order.

The drug controller general of India
The drug controller general of India (DCGI) approves new chemical products introduced into the country. The manufacture, distribution, sale or stocking of any drug requires a licence issued by the authorities established under the Drugs and Cosmetics Act 1940 (the Drugs Act) and the corresponding Drugs & Cosmetic Rules 1945

(the Drugs Rules). Under these provisions, a penalty can be imposed for manufacture, sale, stocking, exhibition or distribution of drugs without a valid licence.

Confusion with INNs

INNs being non-proprietary names cannot be used for coining trademarks. However, there have been several instances where pharmaceutical companies have adopted the strategy of coining trademarks from the stems of INNs. In compliance with Resolution 46.19 passed by the World Health Assembly, which issues directions to member states to discourage the use of INNs to coin trademarks, the Indian legislature included a section in the Trademarks Act prohibiting such registrations (ie, Section 13 mentioned above). However, the registrar has not as yet issued any notification on INNs as envisaged in the Trademarks Act.

Neither the Trademarks Act nor its related rules call for a search of INNs when examining applications for registration of trademarks for pharmaceutical and medicinal preparations and substances in Class 5 of the Nice Classification. Nevertheless, the practice and procedure manual for the administration of the Trademarks Act prescribes guidelines to be observed by examiners while examining applications under Section 13. A pharmaceutical trademark can be refused registration if it is the same or confusingly similar to a notified INN.

However, one can acquire common law rights in a trademark by virtue of use thereof. Therefore the restrictions laid down under Section 13 can be circumvented.

The Drugs Act and the corresponding Drugs Rules require that the generic name of the drug appear on its packaging or label.

Parallel imports and repackaging

Indian approach to parallel imports

Parallel imports of goods bearing registered trademarks are permitted under Indian trademark law, provided such goods are genuine (ie, not materially altered after they are put to use in commerce with the consent of the proprietor of said goods). Once genuine goods are sold in commerce with the proprietor's consent, all associated trademark rights are exhausted. India follows the policy of international exhaustion for the purpose of parallel trade in relation to trademarks. This principle applies to pharmaceutical trademarks.

Provisions under the Trademarks Act

The Trademarks Act does not specifically use the term 'parallel import', yet the concept is addressed under the following provisions:

- Section 29(1) defines the term 'infringement' and Section 29(6)(c) covers "importing or exporting of products under the trademark" within the scope of "infringement by use of a registered trademark".
- Section 30(3) provides that after a person lawfully acquires the goods put in commerce by the proprietor or with its consent, the sale thereafter of such goods by that person will not amount to infringement.
- Section 30(4) provides exceptions and states that if the proprietor has legitimate reasons to oppose further dealings in the goods, Section 30(3) shall not apply.

Thus, while it could be said that parallel imports do not *per se* constitute infringement, the underlying rule is that the cause of action for trademark infringement may be available to a rights holder against an importer that materially alters the rights holder's genuine goods without its consent after those goods have been placed in commerce.

Drug application procedures for import purposes

A person wishing to import drugs manufactured by international pharmaceutical companies is required to obtain an import licence from the DCGI under the Drugs Act and the corresponding Drugs Rules. The licence is granted upon assurance that the exporter complies with Indian production and safety standards. Further, the importer is required to submit a drug sample to the Central Drug Control Organization (CDCO) for testing. On approval, the importer is granted a licence. The importer must supply the following additional documents to the CDCO:

- the import documents;
- the protocols tests and analysis; and
- a sample of the product(s) label(s).

The Indian authorities are empowered under the Drugs Act to prohibit the import of drugs that are of sub-standard quality, misbranded or adulterated, or which have not been labelled in accordance with the law. The importation may also be prohibited in the public interest. Any party can make a written complaint to the DCGI in respect of the quality of a drug, indicating the nature of the complaint and the particulars of the drug. The customs authorities have also been given powers to inspect imported drugs and take appropriate steps under the Customs Act 1962.

Anti-counterfeiting and enforcement

Counterfeit drugs account for a large part of world trade every year. According to statistics published by the European Commission in relation to seizures of counterfeit products at EU borders during 2007, China was identified as the country of origin of the bulk of counterfeit products in most market segments; India, however, was seen as a leading source for counterfeit drugs.

Prevention

Though there are few prevention strategies to combat this global problem, there are ways and means of restricting the flow of fake medicines in the pharmaceuticals market. Mass serialization is one such strategy which has been adopted by Roche India for most of its products sold in India. Under this process, product packaging is given a unique 16-digit alpha-numeric computer-generated code which can be validated by the customer by sending the code through email or SMS to the manufacturing company.

Regulatory framework

The Trademarks Act penalizes the falsification or use of false trademarks and trade descriptions with imprisonment and a fine. The offences under the act are cognizable offences. Police authorities are empowered to search and seize without warrant the instruments involved in committing the offence of counterfeiting.

The Trademarks Act also provides for civil remedies in the form of a suit for infringement wherein the trademark holder can apply for an injunction, seizure of counterfeit goods, damages or accounts of profit. The trademark holder can also institute a suit against counterfeiters for passing off, which is a remedy in common law.

The Drugs Act contains provisions which prohibit the manufacture, sale or import of drugs which are misbranded or counterfeit. It also sets out a number of penalties for breach of these provisions.

Border control measures

The Customs Act prohibits the import or export of goods infringing IP rights and allows for the confiscation thereof. Under the Intellectual Property Rights (Imported Goods) Enforcement Rules, which came into force in 2007, the customs authorities are authorized to suspend clearance of imported goods suspected of infringing IP rights. The newly enacted rules have already been implemented and applied on several occasions.

Advertising

Regulatory framework

The Drugs Act contains provisions relating to the packaging and labelling of prescription drugs and drugs taken only under medical supervision.

In addition to this, the Drugs & Magic Remedies (Objectionable Advertisements) Act 1956 governs the issue of advertising of drugs. Specific diseases are mentioned therein for which no pharmaceutical advertising is allowed.

Misleading advertisements in relation to drugs are prohibited. A 'misleading advertisement' is one that:

- gives false impressions regarding the true character of the drug;
- makes false claims; or
- is otherwise false or misleading in any particular respect.

Prescription drugs

The Drugs Act mandates that prescription drugs are "to be sold on the prescription of a registered medical practitioner only". However, the rules framed by the DCGI, provide that prescription drugs cannot be advertised to the general public. Advertisements in respect of prescription drugs can be published in medical journals but must be solely for the attention of medical practitioners.

Over-the-counter drugs

A voluntary code on the advertising of over-the-counter (OTC) drugs has been established by the DCGI in alliance with the Organization of Pharmaceutical Producers of India (OPPI). The code is followed by OPPI members. The categorization of OTC drugs in India includes vitamins, drugs for coughs and colds, gastrointestinal medicines, pain-killers and certain dermatological products. All such products are widely advertised in the media.

Generic substitution

Indian manufacturers are among the leading producers of generic pharmaceuticals. Such drugs are sold at a much cheaper rate than branded drugs. Due to earlier Indian patent law, which did not allow for product patents for pharmaceuticals, medicines in India are available at substantially lower prices than many other jurisdictions. Moreover, generic substitution is permitted, provided the generic substitute is equivalent to the branded drug in dosage form, strength, safety, route of administration, quality, performance characteristics and proposed use.

Key considerations

Although India is a signatory to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) and has now included a system of protecting pharmaceutical product patents in its patent law, the courts have taken a conservative approach to implementing the regime. Generic manufacturers have been allowed in two landmark decisions to manufacture generic equivalents of branded drugs.

In the *Novartis Case* ((2007) 4 MLJ 1153), the rights of the patentee were critically evaluated. The patent controller upheld the generic manufacturers' plea that a drug manufactured by Novartis and marketed under the trademark GLEEVEC/GLIVEC should not be granted a patent as it was a new form of a known substance and was not patentable under Section 3(d) (which restrains evergreening of patents) of the Patents Act 1970 as amended in 2005. The rejection of the patent for GLEEVEC/GLIVEC allowed other drug manufacturers to produce generic substitutes at a price one-tenth less than the original drug.

Subsequently, Novartis appealed against the decision of the patent controller to the High Court and also challenged Section 3(d) of the Patents Act, arguing that it was not TRIPS-compliant. The High Court dismissed the appeal, stating that it was not an appropriate forum to decide whether any provision of the Indian Patents Act was TRIPS-complaint.

In the *Tarceva Case* (2008 (37) PTC 71 (Del)), Roche sued Cipla for patent infringement and sought an injunction restraining Cipla from selling a generic version of its patented drug marketed under the trademark TARCEVA. Cipla averred that the three-step test for the grant of an injunction demands that the plaintiff demonstrate that:

- there is a *prima facie* case in favour of the plaintiff;
- irreparable injury will be caused to the plaintiff should no injunction be granted;
- the "balance of convenience" favours the plaintiff.

Cipla contended that the second and third grounds were against Roche. The Delhi High Court agreed with Cipla and denied Roche's injunction. It stated that the public interest is one factor to be considered when assessing the third ground of the test and permitted Cipla to continue manufacturing generic versions. Roche has appealed against the order.

Online issues

E-pharmacies

Indian criminals are at the forefront of the illegal online trade in pharmaceuticals at an international level. They market drugs banned in other jurisdictions under different trademarks through e-pharmacies. This illegal trade is worth considerable amounts of money.

In *Kedia v Narcotic Control Bureau* ((2008) 2 SCC 294), the Supreme Court of India refused to grant bail to the chief executive of Xponse Technologies, an individual by the name of Sanjay Kedia. He was arrested by the Narcotic Control Bureau under the provisions of the Narcotic Drugs & Psychotropic Substances Act 1985 for using online facilities to sell drugs illegally and for arranging the supply of banned psychotropic substances to countries such as Canada, Sweden and the United States.

Domain names

The .IN Domain Name Registry was created by the National Internet Exchange of India, a not-for-profit company, to improve internet services in the country. The '.in' country-code top-level domain is a unique symbol of India and is available through a number of registrars.

Indian pharmaceutical companies are actively involved in registering domain names to establish their identity on the Internet. They also prevent their names or their well-known trademarks from being used as a part of domain names of other parties. In *Dr Reddy's Laboratories Ltd v Kosuri* (2001 (58) DRJ 241, 2001 (3) RAJ 122), the court held that the defendant's domain name 'drreddyslab.com' was similar to the plaintiff's DR. REDDY'S mark and, hence, the defendant was restrained from using the domain name. WTR

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